NANORIGO

	EXECUTIVE SUMMARY D2.1
DELIVERABLE TITLE	Evaluation of the identified governance tools for their inclusion in the RGF
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Deliverable D2.1 provides an extensive overview of published/available tools and approaches for the different steps of the NRGF as defined in WP3. The general outputs described in this deliverable are:

i. Tools, approaches and guidances for steps 2 (technical and scientific assessment), 4 (risk evaluation) and 5 (risk management) of the framework.

ii. A newly developed model and library for integrating in vitro data in LCA and RA tools for step 2

iii. Overview of tools for integrating social-economical and ethical aspects (SEA tools), mainly for step 3 but some tools can ben used at other steps as indicated in section 2.2.

Despite the availability of many tools and approaches, none of them is fit for all purposes, making it necessary to incorporate several tools covering different aspects into the RGF. Therefore, the work performed and reported in this deliverable includes a selection of tools that are currently available and most appropriate for risk assessment, LCA, grouping, risk evaluation, risk management, and for the inclusion of socio-economic aspects in the Risk Governance Framework.

A summary of the tools selected for each step is detailed below:

- Step 2 (Scientific and technical assessment). The selection has been performed taking into account the results obtained in previous projects (e.g. caLIBRAte where a selection taking into account stakeholders criteria and evaluation of RA, release and fate tools was performed) and criteria developed in the NanoRigo project (e.g. for grouping, LCA and computational tools and approaches).

- Step 3 (concern assessment). An overview that include tools for incorporating different aspects as social or economical is given. Some of the tools could be also used in other steps. Further development about how to consider these aspects is being performed in WP3.

- Step 4 (evaluation of risk): The selected tools include those that assess the scientific and technical aspects an social, economic, and ethical issues. Decision support systems as MCDA are also included.

- Step 5 (management of risk). The selected tools include those that after evaluation, provide recommendations on management measures, and evaluate those measures. But besides those, additional tools are also included that are useful for Risk management: Nano reference values (NRV), Tools for SbD: SbD implementation platform, Guidelines for Risk management: regulatory, general and for specific sectors, guidelines for waste management.

The use of the selected tools will depend on the availability of high-quality data according to each case's requirements. WP1 will provide databases and data repositories, along with guidances, for

assessing the quality of the data. This material will also be included in the NRGF, and therefore, it will be available for the users of the tools, covering a main gap identified by many stakeholders

Even more, this deliverable describes a new model that has been developed in WP2 to use *in vitro* data in RA and LCIA tools. This model widens the applicability of these tools even when the *in vivo* data required are not available. The library for *in vitro/in vivo* equivalency described in this deliverable makes it possible to use this model in many situations. On the other hand, the PBPK models could also be used for that purpose. The grouping tools selected in this deliverable will also simplify the use of tools by facilitating read across that will decrease the need for testing. Two of the newest grouping tools/approaches will be verified in NANORIGO for its final selection to be included in the RGF.

A final recommendation is to continually update the tools and approaches in the RGF framework with the new content that may become available. In this way, we can cite other ongoing projects that should be considered, e.g results from the sister NMBP-13 projects, Gov4Nano and Riskgone will be important for the final selection of the content of the RGF in the field of developing standards and guidelines for testing that will be important to facilitate the use of the tools and the refinement of different aspects or tools as SIA toolbox and SbD. For the latter, the results obtained in NMBP-15 (SAbyna, SbD4Nano, ASyna, SABYDOMA) will also need to be taken into account as they will provide more tools and recommendations for the development of SbD strategies. For the development and standardisation of methodologies the results of two other ongoing projects as Nanoharmony (aim is developing scientifically reliable test methods based on the existing scientific knowledge and data) and Nanomet (standardisation of methods to characterise the specific properties of NM)

Besides, the outcomes of current running NanoInformatics projects (EU Horizon 2020 NanoInformatIX and NanoSolveIT) will generate a broad spectrum of diverse but interlinked physics-based computational tools (QSARS, PBPKs, fate models etc.), omics models and data-driven models exchanging inputs and outputs. Together they will comprise a multi-scale *in silico* IATA (Integrated Approach for Testing and Assessment) to evaluate nanomaterials' environmental health and safety, installed in state–of–the–art web platforms. In this way, safe-by-design nanomaterials development and nanomaterials Risk Governance will be facilitated.

Considering the vast number of tools for different purposes, it is inevitable to develop a guidance for future users. This guidance can be based on the map of the tools designed in this deliverable. The tight relationship with the case studies in WP5 will determine the usefulness of the platform's content, including tools and will help refine the selection and the user guidance.

As a final remark, an overview of the main contributions of the selected tools to the RGF can be foreseen:

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- Technical tools (databases, evaluation and prediction tools) will help in the identification of nanorisk issues, as well data gaps, research needs, and improvements measures to avoid potential impacts. In general, these tools will be the solid base to build the basic information, which will be the starting point for a later decision on prioritization and action plan design.
- The information obtained through technical tools can be then used to train and form different stakeholders, so they account with a formed opinion on actual problems and recommendations from experts in different fields. SEA tools can support identifying key stakeholders and the training, adapting the information to the objective public.

In order to set priorities and define recommendations and actions, it is necessary to articulate stakeholders identification, information, engagement and dialogue, which the use of SEA tools can achieve.

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